SEP 1 8 2000

K002255

510(K) Summary
Summary of Safety and Effectiveness

Company and Submission Information

Applicant	Wolfe Tory Medical, Inc. 79 West 4500 South, Suite 21 Salt Lake City, UT 84107 (801) 281-3000
Contact	Tim Wolfe, MD
Date Prepared	7/21/00
Classification Name	Applicator, laryngo-tracheal, topical anesthesia 73 CCT
Common/Usual Name	Atomizer
Proprietary Name and Legally Marketed Device	Laryngo-Tracheal Mucosal Atomization Device (MADgic™)
Device Description	Disposable non-sterile device designed for atomizing topical solutions across the nasal and oropharyngeal mucous membranes.
Substantial Equivalence Device	Astra Disposable Spray Cannula K894755

Comparison to Predicate Device

	WT Laryngo-Tracheal Mucosal Atomization Device	Astra Disposable Spray Cannula
Dosage amount	User controlled	Dependent on pump, metered dosage.
Delivery form	Fine particle spray mist	Fine particle spray mist
Cannula shape	Semi-rigid	Semi-rigid
Spray generated by	Piston syringe	Pressurized container
Spray tip diameter	0.157"	0.316"
Materials	Polycarbonate and polyvinylchloride	Polypropylene
Disposable	Yes	Yes

Summary of Research Findings

Endotracheal tube placement elicits numerous physiologic responses in the human organism. These include significant sympathoadrenal responses such as hypertension, tachycardia, elevation of intracranial pressure, increase in intraocular pressure and increase in circulating catecholamines (epinephrine and norepinephrine)[8, 10-18]. In non-pharmacologically paralyzed patients multiple reflex responses also occur including the gag reflex, glottic closure, vocal cord spasm, cough reflex and reflex bronchoconstriction[2-9]. In most situations, these responses do not lead to serious adverse patient outcomes. However, in a substantial number of cases these responses would be best avoided. The solution to these problems is the application of topical anesthetics to the oropharynx and upper airway. An extensive body of literature exists

that demonstrates topical anesthetics attenuate the sympathetic response to intubation while simultaneously reducing or eliminating problems with gag reflex, glottic closure, vocal cord spasm, cough reflex and reflex bronchoconstriction[2-18]. These topical anesthetics are typically applied with laryngotracheal applicator type devices. Wolfe Tory Medical wishes to introduce a new laryngo-racheal applicator called the Laryngo-Tracheal Mucosal Atomization Device.

Conclusions

The process of intubation of the trachea leads to several physiologic and reflex responses by the human body[1]. Application of topical anesthetics to the oropharynx and upper airway prior to intubation results in substantial attenuation of these adverse responses[2-18]. The Laryngo-Tracheal Mucosal Atomization Device safely, gently and effectively applies topical anesthetics to mucosal surfaces. Use of the Laryngo-Tracheal Mucosal Atomization Device to apply anesthetic to the upper airway will attenuate or eliminate these adverse physiologic and reflex responses leading to improved patient outcomes.

References:

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3. **Dyson, D.H., *Efficacy of lidocaine hydrochloride for laryngeal desensitization: a clinical comparison of techniques in the cat.* J Am Vet Med Assoc, 1988. 192(9): p. 1286-8.**
4. **Mallick, A., S.N. Smith, and A.R. Bodenham, *Local anaesthesia to the airway reduces sedation requirements in patients undergoing artificial ventilation [see comments].* Br J Anaesth, 1996. 77(6): p. 731-4.**
5. **McCrirrick, A. and J.A. Pracilio, *Awake intubation: a new technique [see comments].* Anaesthesia, 1991. 46(8): p. 661-3.**
6. **Mongan, P.D. and R.D. Culling, *Rapid oral anesthesia for awake intubation.* J Clin Anesth, 1992. 4(2): p. 101-5.**
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8. **Sutherland, A.D. and R.T. Williams, *Cardiovascular responses and lidocaine absorption in fiberoptic- assisted awake intubation.* Anesth Analg, 1986. 65(4): p. 389-91.**
9. **Viguera, M., *et al.*, *[Efficacy of topical administration of lidocaine through a Malinckrodt Hi-Lo Jet tube in lessening cough during recovery from general anesthesia].* Rev Esp Anestesiol Reanim, 1992. 39(5): p. 316-8.**
10. **Gaumann, D.M., *et al.*, *Effects of topical laryngeal lidocaine on sympathetic response to rigid panendoscopy under general anesthesia.* ORL J Otorhinolaryngol Relat Spec, 1992. 54(1): p. 49-53.**

11. Giorgi, L., *et al., [Topical laryngo-tracheal anesthesia and intraocular pressure in anesthesia for ophthalmic surgery].* Minerva Anestesiol, 1994. 60(1-2): p. 43-7.
12. Konrad, C., *et al., Is an alkalinized lignocaine solution a better topical anaesthetic for intratracheal application?* Eur J Anaesthesiol, 1997. 14(6): p. 616-22.
13. Latorre, F., *et al., [Fiberoptic intubation and stress].* Anaesthesist, 1993. 42(7): p. 423-6.
14. Lehtinen, A.M., *et al., Effect of intratracheal lignocaine, halothane and thiopentone on changes in plasma beta-endorphin immunoreactivity in response to tracheal intubation.* Br J Anaesth, 1984. 56(3): p. 247-50.
15. Stevens, J.B., P.A. Vories, and S.C. Walker, *Nebulized tetracaine attenuates the hemodynamic response to tracheal intubation.* Acta Anaesthesiol Scand, 1996. 40(6): p. 757-9.
16. Stoelting, R.K., *Circulatory response to laryngoscopy and tracheal intubation with or without prior oropharyngeal viscous lidocaine.* Anesth Analg, 1977. 56(5): p. 618-21.
17. Venus, B., V. Polassani, and C.G. Pham, *Effects of aerosolized lidocaine on circulatory responses to laryngoscopy and tracheal intubation.* Crit Care Med, 1984. 12(4): p. 391-4.
18. Yusa, T., *et al., [Effects of intratracheal lidocaine spray on circulatory responses to endotracheal intubation].* Masui, 1990. 39(10): p. 1325-32.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 8 2000

Mr. Tim Wolfe
Wolfe Tory Medical, Inc.
79 West 4500 South, Suite 21
Salt Lake City, UT 84107

Re: K002255
Laryngo-Tracheal Mucosal Atomization Device (Madgic)
Regulatory Class: II (two)
Product Code: 73 CCT
Dated: July 21, 2000
Received: July 25, 2000

Dear Mr. Wolfe:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications for Use

Ver/ 3 - 4/24/96

Applicant: Wolfe Tory Medical, Inc.

510(k) Number (if known): K002255

Device Name: Laryngo-tracheal Mucosal Atomization Device (MADgic™)

Indications For Use:

Intended for the application of topical anesthetics to the oropharynx and upper airway region.

X PRESCRIPTION USE or ___ OVER-THE-COUNTER USE

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Division of Cardiovascular & Respiratory Devices
510(k) Number K002255

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Per 21 CFR 801.109)

(Optional Format 1-2-96)